510 (k) Summary
as required by section 807.92(c)

DEC 1 8 2001

K010925

Subscribers Name & Address

Siemens-Elema AB
Electromedical Systems Division, Life Support Systems
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Contact Person for this submission: Anders Palm
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Director, of RA/QA, (732) 321 4765, at Siemens Medical Systems, Iselin, NJ

Trade Names

Servo^i **Ventilator System**
Accessory : **Siemens Servo Ultra Nebulizer 345**

Device Classification

Common Name	*Classification Number*	*Class*	*Regulation Number*
Ventilator, Continuous (Respirator)	73 CBK	II	868.5895
Nebulizer (Direct Patient Interface)	CAF	II	868.5630

Predicate Device Identification

Legally marketed devices to which equivalence is being claimed	*510(k) #*
Siemens Servo Ventilator 300 A	K970839
Siemens Servo Ultra Nebulizer 345	K960854
Evita 4	K980642

Device Description (for detailed description see Section F)

The Servo^i Ventilator System consists of a Patient unit where gases are mixed and administered, and an User Interface where the settings are made and ventilation is monitored.
The ventilator delivers controlled or supported breaths to the patient, with either constant flow or constant pressure, using a set oxygen concentration. The Servo^i Ventilator System will be available in three versions, Infant, Adult and Universal. The Universal will cover all patient ranges (0,5 – 250 Kg). The ventilator functionality is controlled by software and upgrading to Universal and extended functionality is possible.

Servo^i Ventilator System will produce visual and audible alarms and the event is saved in the log. The system contains provisions for battery modules to supply the system during in-hospital transport or in the case of mains power failure.

Accessories for nebulization, same as for SV300A, can be used and the Nebulizer driver is controlled by the software in the Servo^i Ventilator System

Intended Use of the Device:

The Servo^i Ventilator System is intended for short- or long-term use in general and critical ventilatory care. It can be used for ventilation with acute or chronic ventilatory problems and for post-operative ventilation.

The Servo^i Ventilator System is intended for treatment and monitoring of the patient who lacks spontaneous breathing or has insufficient breathing ability.

Intended operator:

Servo^i is a ventilator system with advanced functionality. It may be used only by professional health care providers who have sufficient experience in ventilator treatment.

Intended Patient Populations:

The Servo^i Ventilator System is intended for use on the infant to adult patient populations.

Servo^i Infant version for the infant/pediatric patient (with weight 0,5-30 Kg)
Servo^i Adult version for the adolescent/ adult patient (with weight 10-250 Kg)
Servo^i Universal version for the infant/ pediatric/ adolescent/adult patient.

Intended Use Environment:

The Servo^i Ventilator System is designed to be used at the bedside and for in-hospital transport.
The Servo^i Ventilator System is not intended to be used with any anesthetic agents.
The Servo^i Ventilator System is not compatible for use in a MRI magnetic field

Summary of technological characteristics of Device and Predicate Device:

The functionality for the Servo^i Ventilator System is equivalent to the Siemens Servo Ventilator 300A and partly also to Draeger Evita 4. The Siemens Servo Ventilator SV 300A was been found substantially equivalent under 510(k) file number K970839 and Draeger Evita 4 file number K980642.
The technical differences are

- a more physical compactness,
- simplified user interaction for fast and reliable user operation,
- use of modern components for less maintenance and smaller sizes,
- software controlled upgrading capabilities
- data storage possibilities.

The technology used is assessed and animal studies show that the Servo^i Ventilator System has the equivalent clinical performance.

The external part of the Nebulizer is identical to the version found substantially equivalent (Siemens Servo Ultra Nebulizer 345) in the 510(k) file number K960854. The power supply is incorporated into the Servo^i Ventilator System with the technological difference to be software controlled, including a timed operation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 8 2001

Ms. Diane Wurzburger
Siemens Elema AB
c/o Siemens Medical Ssytems, Inc.
186 Wood Avenue South
Iselin, NJ 08830-2770

Re: K010925
Servo[i] Ventilator System
Regulation Number: 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II (two)
Product Code: CBK
Dated: December 10, 2001
Received: December 11, 2001

Dear Ms. Wurzburger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

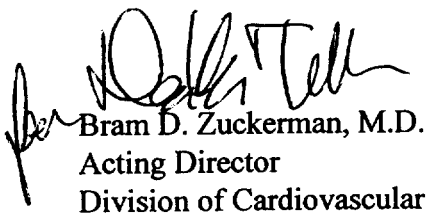
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Intended Use Statement

510(k) Number (if known): *K010925*

Device Name: *Servo[i] Ventilator System*

Indications for Use:

The Servo[i] Ventilator System is intended for treatment and monitoring of patients in the range of neonates, infants and adults with respiratory failure or respiratory insufficiency. Servo[i] is a ventilator system to be used only by healthcare providers in hospitals or healthcare facilities and for in-hospital transport.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K010925